

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/996,588	DORIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita Mitra	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/14/05.
2. ☒ The allowed claim(s) is/are 71-80,83-128 and 263-291.
3. ☒ The drawings filed on 14 September 2005 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date <u>9/14,05</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input checked="" type="checkbox"/> Other <u>TD approved</u>.</li> </ol> |
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## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' amendment and response to office action dated August 30, 2005, filed on September 14, 2005, is acknowledged. Claims 81, 82 and 129-262 have been canceled. Therefore, claims 71-80, 83-128 and 263-291 are currently pending.

### ***Response to Amendments and Remarks***

#### **Information Disclosure Statement**

Supplemental information disclosure statement is acknowledged.

#### **Objection to Drawings**

Objection to Drawings is withdrawn in view of Applicants' amendment.

#### **Objection to the Specification**

Objection to the specification is withdrawn in view of Applicants' providing an abstract.

#### **Claim Rejections – Nonstatutory Double Patenting**

Rejection of claims 71, 73, 78, 79, 109, 110 and 263-269 is withdrawn in view of the approval of Terminal Disclaimer submitted by applicants.

An **Examiner's amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

### ***Amendment to the Specification***

1. The continuity data has been entered on the page 1, line 1 of the specification, which reads as:

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This application is a continuation of US 09/443099, filed November 18, 1999, now abandoned, which is a division of US 08/973211, filed June 11, 1999, US Patent 6323326, which is a 371 of PCT/US96/09980, filed June 7, 1996, which is a continuation of US 08/473688, filed June 7, 1995, now abandoned, which is a continuation of US 08/477677, filed June 7, 1995, now abandoned. The entire content of these applications is herein incorporated by reference.

2. The Figure Numbers in the Brief Description of the Drawings have been amended to read as below:

Figure 16 as Figure 16 A-B

Figure 18 as Figure 18 A-B

Figure 21 as Figure 21 A-B

Figure 23 as Figure 23 A-C

Figure 27 as Figure 27 A-B

Figure 28 as Figure 28 A-B

### *Reasons for Allowance*

The following is an examiner's statement of reasons for allowance:

Muteins of TFPI and TFPI-2 are disclosed in US serial number 08/286530 (now US Patent 6,103,500 at col. 6, lines 48-67), which has been incorporated by reference in the instant application (see specification page 20).

The prior art of record does not teach or suggest a composition that is used for the correct refolding of recombinant human TFPI protein, wherein said composition comprising a polypeptide of said TFPI selected from the group consisting of TFPI having an amino acid sequence of native TFPI and having one further amino acid which is an amino terminal alanine or a mutein, and further comprising from 200 mM arginine to 300 mM arginine. Wherein, the unexpected property of arginine of the claimed TFPI composition that increases the TFPI solubility by a factor of 100 (see specification page 10) is not taught or suggested in the prior art.

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Thus, the composition comprising arginine of the instant application is novel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

Claims 71-80, 83-128 and 263-291 are allowed.

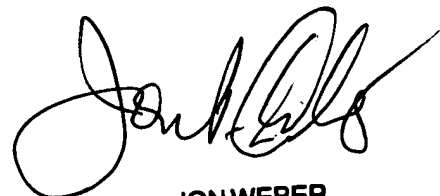
### *Inquiries*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

September 30, 2005



JON WEBER  
SUPERVISORY PATENT EXAMINER